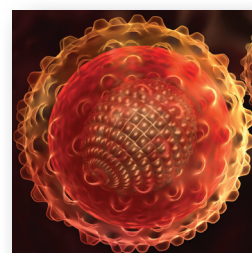


Huge Growth Seen in Hepatitis C Market

Kunj Gohil, PharmD, RPh



Hepatitis C is a significant public health concern that affected approximately 100.2 million patients globally in 2012. Even more alarming, only 0.4 million were treated that year, showing the need for increased screening and timely diagnosis.

Treatment options in 2012 yielded sales of \$4.4 billion globally and \$2.1 billion in the U.S. This is expected to rise to

Dr. Gohil is a Post Doctoral Fellow with Medical Services at MediMedia Managed Markets in Yardley, Pennsylvania.

\$10.8 billion globally and \$6.5 billion in the U.S. by 2022 as pharmaceutical makers develop treatments with improved outcomes and safety profiles.¹

Traditional treatment consisted of an interferon, associated with severe flu-like symptoms, and ribavirin, associated with severe anemia.² In 2013, Gilead was the first to develop a novel treatment option for hepatitis C, but this regimen still requires ribavirin and, potentially, interferon.³ Future therapies, which use neither of these traditional drugs, will revolutionize management of this disease.⁴

REFERENCES

1. GlobalData. *Hepatitis C Virus: Global Drug Forecast and Market Analysis to 2022*. May 2014.
2. Lexicomp. Philadelphia, Pennsylvania: Wolters Kluwer Health.
3. Sovaldi (sofosbuvir), package insert. Foster City, California: Gilead Sciences, Inc.; December 2013.
4. Swan T. Hepatitis C drug development catapults onward. Pipeline Report. June 2013. Available at: www.pipelinereport.org/2013/hcv. Accessed May 20, 2014. ■

Future Therapies

Drug Manufacturer	Status	Indication	Regimen Information	Pivotal Studies	Expected Approval	Anticipated Peak Year Sales/Pricing
Ledipasvir/ sofosbuvir Gilead	NDA filed	HCV (gen 1)	One pill daily, fixed dose, 8 or 12 wks, interferon-free	ION 1, 2, 3	Oct. 10, 2014	\$4,261M in 2019; combination expected to be priced about 85% over telaprevir in U.S.
ABT-450/r + ombitasvir (ABT-267) + dasabuvir (ABT-333) AbbVie/Enanta	NDA filed	HCV (gen 1): For treatment-naïve, treat- ment-experienced, HIV co-infected, and cirrhotic patients	Oral, interferon- free, twice daily, 12–24 wks	SAPPHIRE 1, 2 TURQUOISE 1, 2	Late 2014 or early 2015	\$3,110M in 2018; combination expected to be priced about 85% over telaprevir in U.S. and to replace interferon-based regimens
Daclatasvir + asunaprevir	NDA filed	HCV (gen 1b)	Oral, interferon- free, 24–48 wks	HALLMARK- DUAL	2014	Daclatasvir, \$795M in 2018; expected to be priced about 40% over telaprevir in U.S. Asunaprevir, \$91M in 2019; ex- pected to be priced about 10% over the most prescribed peginterferon in U.S.
Daclatasvir + sofosbuvir	Phase 3	HCV (gen 1–6)	Oral, interferon- free, 8–36 wks	ALLY 1, 2, 3	2015 or 2016	
Daclatasvir + asuna- previr + BMS-791325 Bristol-Myers Squibb	Phase 3	HCV (gen 1)	Oral, interferon- free, 12 wks	UNITY 1, 2	2015	Fixed-dosed combination expected to be priced about 85% over telaprevir in U.S.
Faldaprevir Boehringer Ingelheim	NDA filed	HCV (gen 1)	Oral, interferon- sparing, 12–24 wks	STARTverso 1, 2, 3, 4	Late 2014	\$275M in 2018; expected to be priced about 40% over telaprevir in U.S.

Gen = genotype; HIV = human immunodeficiency virus; M = million; HCV = hepatitis C virus infection; NDA = new drug application; wks = weeks

Sources: GlobalData; Redbook; FDA

Current Therapies

Drug / Manufacturer	Approval Date	Indication	Regimen Information	Cost of Course of Therapy
Sovaldi (sofosbuvir) / Gilead	Dec. 6, 2013	Gen 1–4 chronic HCV	Oral (q.d., 12–24 wks)	12-wk regimen: \$84,000
Olysio (simeprevir) / Janssen	Nov. 22, 2013	Gen 1 chronic HCV	Oral (q.d., 12 wks)	12-wk regimen: \$66,360
Incivek (telaprevir) / Vertex	May 23, 2011	Gen 1 chronic HCV	Oral (2 tabs t.i.d., 12 wks)	12-wk regimen: \$11,025.85
Victrelis (boceprevir) / Merck	May 13, 2011	Gen 1 chronic HCV	Oral (4 caps t.i.d., 24–44 wks)	24-wk regimen: \$3,343.36

Caps = capsules; Gen = genotype; HCV = hepatitis C virus infection; q.d. = once daily; t.i.d. = three times daily; tabs = tablets; wk = week

Sources: GlobalData; Redbook; FDA; prescribing information for Sovaldi, Olysio, Incivek, and Victrelis